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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/227,687      | 01/08/1999  | FRANCIS P. TALLY     | CPI98-03P9MA        | 7885             |

34103 7590 02/25/2003

CUBIST PHARMACEUTICALS, INC.  
65 HAYDEN AVENUE  
LEXINGTON, MA 02421

EXAMINER

LEFFERS JR, GERALD G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 02/25/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/227,687

Applicant(s)

TALLY ET AL.

Examiner

Gerald G Leffers Jr.

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 67-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67,68,70,72-76,78-85,87,89-91,93-98,100-112,114-120 and 122-131 is/are allowed.
- 6) ☒ Claim(s) 69,86,99,113 and 121 is/are rejected.
- 7) ☒ Claim(s) 71,77,88 and 92 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 27.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt is acknowledged of a response filed 9/23/02 as Paper No. 25, in which several amendments were made to the then pending claims. Following a telephonic interview on 10/18/02, a supplemental response was filed on 12/12/02 as Paper No. 26. An interview summary for this interview is attached to the instant action. In Paper No. 26 the then pending claims were cancelled (claims 1-2, 6-12, 23-27, 50-54 and 56-58) and new claims were added (claims 59-123).

It is noted that claim numbers 59-66 had already been used during the course of prosecution of the instant application. The newly submitted claims were therefore renumbered from the next available unused claim as claims 67-131 (Rule 1.126). Claims 67-131 are pending in the instant application.

Any rejection of record in the previous office actions that is not addressed in this action is withdrawn. All claim objections and rejections herein refer to the renumbered claims. Because the new grounds of rejection made in the instant action were necessitated by applicants' amendment of the claims in Paper No. 26, the instant action is FINAL.

### ***Claim Objections***

Claims 71, 77, 88, 92 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of the claims comprises a limitation that the protein target component of the claim upon which they depend comprises a gene product. It

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is unclear how this limitation can further limit the independent claim in that it is unclear how a protein target component can not comprise "a gene product".

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69, 86, 99, 113 and 121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is a new rejection necessitated by applicants' amendment of the claims in Paper No. 26.**

Claims 69, 86, 99, 113 and 121 are vague and indefinite in that the claims specify in step (iii) that an observation of an effect on cells grown in culture (e.g. inhibited growth, inhibited infection or phenotypic effect) dictates that the expressed biomolecule (or peptide) causes the observed effect, while indicating in step (c) of the claim that an observation of the effect on the cells in vivo subsequent to step (iii) indicates the biomolecule (or peptide) causes the effect. As the claims are written, it is not necessarily clear that one has achieved completion of the method after the in vitro step recited in step (iii) or after the in vivo step of step (c). To avoid possible confusion as to the point at which the claimed method is completed, it is suggested that 1) the independent claims upon which the rejected claims are dependent be modified to state in the preamble that they are drawn to methods of determining the recited effect (e.g. inhibitors of cell growth, inhibitors of infection or producing a phenotypic effect) for cells in vivo, 2) the rejected claims indicate at the end of step (iii) the effect (i.e. inhibition of growth, phenotypic effect, etc.)

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is observed in culture, and 3) the independent claims indicate in step (c) the effect is seen in cells in vivo so that the end result of the claimed method matches the preamble.

### *Conclusion*

Claims 69, 86, 99, 113 and 121 are rejected. Claims 71, 77, 88 and 92 are objected to for reasons given above. Claims 67-68, 70, 72-76, 78-85, 87, 89-91, 93-98, 100-112, 114-120 and 122-131 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

  
Ggl  
February 23, 2003

DAVID GUZO  
PRIMARY EXAMINER  
